K0 8 2657

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**510(k) Summary**
(per 21 CFR 807.92(c))

## 1. Applicant

Medivent Limited.
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London
NW4 1AA
UK

Contact Person: Shahar Hayek, Managing Director
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Date Prepared: August 25, 2008

## 2. Device Name

Trade Name: RTX Respirator
Common/Usual Name: Non-Invasive Cuirass Respirator
Classification Name: External negative pressure ventilator
Regulation Number: 868.5935
Product Codes: BYT
Classification: II
Classification Panel: Anesthesiology

## 3. Predicate Devices

The RTX Respirator is substantially equivalent to the following devices:

| 510(k) Number | Device | Manufacturer |
|---|---|---|
| K924341 | Hayek Oscillator | Respironics |
| K841529 | Servo Ventilator 900C | Siemens |
| K884098 | Thairapy ™ Bronchial Drainage System, Model 101 now known as The Vest Airway Clearance System | Originally manufactured by American Biosystems but now manufactured by Hill-Rom |

## 4. Intended Use

1. Ventilation –

   The RTX Respirator is indicated for external ventilation of the lungs resulting in gas exchange.

2. Secretion Clearance –
   Also for use in assisting patients with secretion clearance management as indicated by standard medical convention

The RTX Respirator is for use in adult and pediatric patient populations. The RTX is not for use in out-of-hospital transport. For prescription use only.

## 5. Description of the Device

The RTX Respirator is an external high and low frequency respirator, which controls both phases of the respiratory cycle. It consists of a lightweight flexible cuirass, tubing and a power unit with a keypad and display screen. The Cuirass is available is eleven (11) sizes to cover various patient populations and sizes. The Cuirass contains a disposable seal and is attached to the patient via Velcro and nylon straps.

The RTX Respirator ventilates by decreasing and then increasing the pressure within the cuirass chamber, providing either controlled, triggered or synchronized inspiration and expiration. The negative pressure creates expansion of the chest bringing about inspiration. The positive phase creates positive pressure on the chest and therefore creates expiration.

## 6. Summary of the Technical Characteristics

### 6.1 Electrical Testing

The RTX Respirator was tested and found to be compliant to IEC 60601-1-2, CISPR 11:2004, Class 4, IEC 61000-3-2/3, IEC 61000-4-2/3/4/5/6/8/11, and IEC 60601-1.

### 6.2 Clinical Evaluation

A comparative clinical study was performed and the RTX Respirator was shown to exhibit a similar pattern of results to the predicate Hayek Oscillator (K924341) and at times had significantly better results. Also, a review of recent publications on the RTX Respirator showed it to be a safe and effective device.

## 7. Safety & Effectiveness

There are no known substantial differences between the RTX Respirator defined in this 510(k) submission and the predicate devices. They have the same or similar intended indications for use and any differences in technological characteristics do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Medivent Limited
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K082657
Trade/Device Name: RTX Respirator
Regulation Number: 21 CFR 868.5935
Regulation Name: External Negative Pressure Ventilator
Regulatory Class: II
Product Code: BYT
Dated: September 29, 2008
Received: September 30, 2008

Dear Mr. Kogoma:

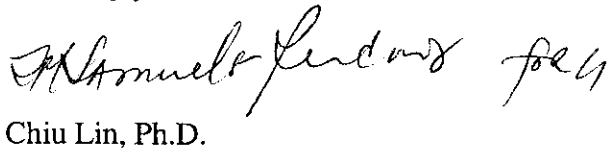
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): _____

Device Name: RTX Respirator

Indications for Use:

1) Ventilation –

The RTX Respirator is indicated for external ventilation of the lungs resulting in gas exchange.

2) Secretion Clearance –
Also for use in assisting patients with secretion clearance management as indicated by standard medical convention

The RTX Respirator is for use in adult and pediatric patient populations. The RTX is not for use in out-of-hospital transport. For prescription use only.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082657

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)